

# A study to assess if a large-scale clinical trial giving colchicine to dialysis patients is feasible

<b>Submission date</b> 26/12/2024	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/01/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/02/2025	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Colchicine is a drug that has been available for decades for the treatment and prevention of gout. Recent studies have shown that colchicine decreases the number of heart attacks and strokes. There are also reasons to believe colchicine may improve outcomes for arteriovenous fistulas and grafts.

At present, colchicine is often avoided in dialysis patients due to concerns of accumulation, but this is not based on robust evidence. Patients on haemodialysis also take a number of medications already and have significant comorbidity. Therefore, it is possible that a higher proportion would have difficulty tolerating colchicine. These concerns mean that a large trial assessing the potential benefits of colchicine in this population cannot begin without further data on feasibility.

This feasibility study will establish whether low-dose colchicine is tolerated and acceptable to dialysis patients and will help us to plan recruitment to future clinical trials. If feasibility is confirmed, there are then strong rationales for large clinical trials exploring the effect of colchicine on both death rates and vascular access outcomes in dialysis patients.

### Who can participate?

Patients aged 18 years and over undergoing haemodialysis

### What does the study involve?

The researchers will give colchicine 0.5 mg once a day to 100 dialysis patients for 3 months and 2 weeks. They will monitor patients for side effects through regular interviews, and see how many continue to take it for the planned duration. They will check the results from the patients' routine monthly bloods taken on haemodialysis, so no additional blood-taking visits will be needed. At the beginning and the end of the study, patients will be asked to complete a survey about their quality of life.

### What are the possible benefits and risks of participating?

Patients may not directly benefit from taking part in this study, but the information gained from their participation may help to improve the healthcare of patients in the future. It is possible that colchicine may reduce the risks of heart diseases and strokes, but we cannot say this for certain until we have completed this and future studies.

There might be a risk of experiencing side effects from colchicine. Common side effects may include diarrhoea, nausea, vomiting or stomach discomfort. Rarer side effects include low white blood cell levels, fevers and muscle, liver or nerve problems. The risk of this is very small, and in many of the reports there were other factors contributing to severe side effects, such as the use of certain drugs that may interact with colchicine.

Extensive clinical experience has shown colchicine is safe and effective in the general population. At present, there is limited data on the frequency of side effects among patients on haemodialysis. This study has been discussed with the nephrologists and pharmacists in our unit, and they support this study and do not have safety concerns.

The risk of side effects is higher with higher doses of colchicine. The researchers are currently using the lowest dose of colchicine available, which is 3-4 times less than the standard dose used for treating acute gout. The side effects are also reversible once colchicine has been stopped. Patients will be closely monitored for any side effects through regular blood tests and interviews during the study.

Where is the study run from?

Guy's and St Thomas' Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

October 2024 to November 2027

Who is funding the study?

Guy's and St Thomas' Hospital NHS Foundation Trust (UK)

Who is the main contact?

Dr Dorothy Wong, [dorothy.wong@kcl.ac.uk](mailto:dorothy.wong@kcl.ac.uk)

## Contact information

### Type(s)

Scientific, Principal investigator

### Contact name

Dr Michael Robson

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

335421

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

Nil known

## **Study information**

**Scientific Title**

Colchicine and dialysis patients; a feasibility study

**Acronym**

CAD

**Study objectives**

It is feasible to carry out future definitive full-scale trials of colchicine in patients on haemodialysis based on adherence and recruitment.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 04/11/2024, Wales REC 6 (Floor 4, Institute of Life Science 2, Swansea University, Singleton Park, Swansea, SA2 8PP, United Kingdom; +44 (0)2922940911; Wales.REC6@wales.nhs.uk), ref: 24/WA/0277

**Study design**

Open-label single-centre single-arm feasibility study

**Primary study design**

Interventional

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

Haemodialysis

**Interventions**

Colchicine 0.5 mg once daily orally will be given for 3 months and 2 weeks to all enrolled patients

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Colchicine

**Primary outcome(s)**

The primary outcome is feasibility and the decision to progress to a full-scale trial based on:

1. Consent rate measured using the number of patients approached, screened, and included in the study over 1.5 years
2. Colchicine continuation rate measured using the number of patients who continued colchicine until the end of the study

**Key secondary outcome(s)**

1. To demonstrate the feasibility of data collection, including the following:

1.1. Health-related quality of life (QoL) measured using the EQ-5D-5L and vascular access-related QoL measured using the Vascular Access Specific Quality of life measure (VASQoL) at baseline and study end

1.2. Vascular access events and interventions (radiological or surgical) measured using data collected in Case Report Forms throughout the study

1.3. Adverse events (including leukopenia, raised CK, gastrointestinal, and neurological) measured using data collected in Case Report Forms throughout the study.

Feasibility will be considered to be demonstrated if complete data is collected for more than 80% of participants for each of the above outcomes.

2. To establish the utility of the EHR (electronic health records), a dataset from the EHR will be extracted and compared to the data entered into the eCRF database at the end of the study.

**Completion date**

01/11/2027

**Eligibility****Key inclusion criteria**

1. Anyone who is undergoing haemodialysis
2. Aged 18 years or over
3. Able to give informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Already taking colchicine for a clinical indication.
2. Taking a drug known to increase colchicine levels.
3. Has a previously documented intolerance of or allergy to colchicine
4. Has a history of chronic liver disease, or abnormal liver function (i.e. ALT > 1.5 x upper limit of normal). Patients with a history of hepatitis are eligible provided these limits are not exceeded.

**Date of first enrolment**

01/04/2025

**Date of final enrolment**

31/12/2026

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Guy's and St Thomas' Hospitals**

Trust Offices

Guy's Hospital

Great Maze Pond

London

United Kingdom

SE1 9RT

## Sponsor information

### Organisation

King's College London

### ROR

<https://ror.org/0220mzb33>

### Organisation

Guy's Hospital

### ROR

<https://ror.org/04r33pf22>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Guy's and St Thomas' NHS Foundation Trust

### Alternative Name(s)

### Funding Body Type

Government organisation

### Funding Body Subtype

Local government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

Pseudonymised clinical and research data for the study will be stored on an electronic database (REDCap). All requests for access to the data entry system must be authorised by the Chief Investigator. All requests for data exports must be authorised by the trial statistician. Following the completion of the trial all documentation and trial data will be kept for at least 15 years.

The datasets generated during and/or analysed during the current study will be available upon request from Dr Michael Robson (michael.robson@kcl.ac.uk).

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 2	20/11/2024	03/01/2025	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes